EU GPP Criteria for Electrical and Electronic Equipment used in the Health Care Sector (Health Care EEE)

Green Public Procurement (GPP) is a voluntary instrument. This document provides the EU GPP criteria developed for electrical and electronic equipment used in the health care sector.

Detailed information about the health care EEE product group, the reasons for selecting these criteria, information about related legislation and other sources can be found in the Technical Background Report.

EU GPP criteria are usually presented in two sets, core and comprehensive criteria:

- The core criteria are those suitable for use by any contracting authority across the Member States and address the key environmental impacts. They are designed to be used with minimum additional verification effort or cost increases.
- The comprehensive criteria are for those who wish to purchase the best products available on the market. These may require additional verification effort or a slight increase in cost compared to other products with the same functionality.

Since this is a new product group, mainly core criteria have been set. The comprehensive criteria are at the end of the document (nr. 17 and 18).

The criteria have been developed to encourage the purchase of Healthcare EEE with reduced environmental impacts **while always giving priority to the safety and welfare of patients as well as that of medical staff, technicians and maintenance personnel**.

Acronyms can be found in appendix 19.

1. Definition and Scope

For the purposes of these criteria, health care EEE includes both high and low voltage equipment. It covers the complete care cycle as referred to in the Medical Devices Directive 93/42/EEC, Article 1.2. The Medical Devices Directive includes medical devices used for the purpose of, for example, prevention, diagnosis, treatment monitoring, alleviation and rehabilitation. According to the standard EN IEC 60601-1 medical electrical equipment is defined as:

- Medical Electrical Equipment provided with not more than one connection to a particular supply mains (immobile equipment) and intended to diagnose, treat, or monitor the patient under medical supervision and which makes physical or electrical contact with the patient and/or transfers energy to or from the patient and/or detects such energy transfer to or from the patient. The equipment includes those accessories as defined by the manufacturer which are necessary to enable the normal use of the equipment.

- Mobile Medical Electrical Equipment which is transportable equipment intended to be moved from one location to another between periods of use while supported by its own wheels or equivalent means.

Regarding product groups excluded from the scope, see the Technical Background Report.

The procurement criteria in this document are intended to be used in the procurement of the following products:

- CPV 33157000-5: Anaesthesia equipment- ventilator (intensive care ventilator excl. transport ventilator, anaesthesia ventilator excl. home ventilators)
- CPV 33195100-4: Bed side monitoring equipment
- CPV 33115100-0: Computed Tomography (CT)
- CPV 33123200-0: Electrocardiographic (ECG) equipment, diagnostic
- CPV 33168100-6: Endoscopic equipment (camera unit, endoscope, light, air pump)
- CPV 39330000-4: Flusher disinfector
- CPV 33181100-3: Haemodialysis equipment
- CPV 33161000-6: HF, RF Surgery, diathermy equipment, bipolar, mono polar
- CPV 33152000-0: Incubators for babies, permanent
- CPV 33194110-0: Infusion pumps and syringe pumps
- CPV 33157400-9: Intensive care equipment – active respiratory gas humidifier
- CPV 33169100-3: Laser instruments for surgery
- CPV 33111610-0: Magnetic Resonance Imaging (MRI)
- CPV 39711120-6: Medical freezers
- CPV 31524110-9: Medical lighting- surgical lamps
- CPV 33191110-9: Medical sterilizer
- CPV 33160000-9, 33162000-3: Patient warming systems (blankets, pads, mattresses)
- CPV 33112200-0: Ultrasound, excl. therapeutic
- CPV 33191000-5: Washer disinfector
- CPV 33111000-1, 33111650-2: X-ray (including Mammography, excl. osteoporosis)

2. Key environmental impacts

The proposed GPP criteria are designed to reflect the key environmental impacts. This approach is summarised as follows:

KEY ENVIRONMENTAL ASPECTS AND IMPACTS	GPP APPROACH
• Energy consumption in the use phase (e.g. emission of GHG emissions and air pollution in energy production)	• Purchase energy efficient equipment
	• Purchase equipment with low power mode
	• Purchase equipment supplied with green performance management instructions
	• Purchase equipment with a metering device
	• Ensure the appropriate and energy efficient functioning of the equipment through a needs' assessment and the provisions of training on energy efficiency
• Water consumption in the use phase: dialysis, disinfectors (Water scarcity)	• Purchase water efficient dialysis and disinfectant equipment
• Gas consumption in the use phase: anaesthesia equipment (for example emission of greenhouse gasses)	• Purchase low-flow anaesthesia equipment
• Use of refrigerants in medical freezers (Global warming, ozone depletion)	• Purchase medical freezers containing refrigerants with low GWP
• Use of materials (Scarcity of resources)	• Product longevity
• Content of hazardous chemicals	• Purchase equipment from suppliers with chemicals managements systems

The order of impacts does not necessarily reflect their importance.

3. EU GPP Criteria for health care EEE

The criteria under 3.1 are recommended for use for the purchase of all types of equipment. 3.2 is setting out energy efficiency requirements and 3.3 water efficiency requirements for different types of equipment.

As mentioned above, mainly core criteria have been set. The comprehensive criteria are at the end of the document (17.-18.).

3.1 Criteria for all types of equipment

Core criteria

SUBJECT MATTER

Purchase of electrical and electronic equipment used in the health care sector with reduced environmental impact.

SELECTION CRITERIA

1. Chemicals management system

The tenderer shall have a chemicals management system in place with dedicated resources, the necessary expertise and with documented routines and instructions in order to ensure that the tenderer is aware of the presence of substances in the product(s) purchased under this contract which have been included in the Candidate List of Substances of Very High Concern (SVHC) identified under Article 57 of Regulation (EC) No 1907/2006 (REACH regulation), including possible additions to the Candidate List. This includes:

- that information about the presence of the listed substances have been requested from suppliers, including new additions to the list (within 1 month after the publication of a revised list by ECHA);
- a systematic collection and archiving of received information on SVHC in the REACH Candidate List in the products purchased under this contract ; i.e. record-keeping and monitoring procedures (for example, regular inspections of documentation regarding content of Candidate List Substances in the product and spot checks of chemical content (laboratory analysis reports)), in order to evaluate collected information for inconsistencies.

Verification: Tenderers shall confirm that they have above described routines and instructions in place and describe the system for documentation, monitoring and following-up and the resources allocated (time, personnel and their expertise). Spot checks of the reports described in the requirement above can be carried out[1].

[1] For further guidance, see the ECHA Guidance to substances in article, http://echa.europa.eu/ or similar guidance e.g. www.cocir.org, or other industry guidance on REACH.

TECHNICAL SPECIFICATIONS

2. User instructions for green performance management

A guide shall be provided with instructions on how to maximise the environmental performance of the particular medical equipment in written form either as a specific part of the user manual, or in digital form accessible via the manufacturer's website, or on a CD, or in paper format on the packaging or on documentation accompanying the product. The instruction manual shall be made available together with the equipment. The documentation shall, as a minimum requirement and without detriment to the clinical performance of the equipment, include the following:

- Instructions for users on how to use the equipment to minimize the environmental impact during installation, use, service and recycling/disposal , including instructions on how to minimize consumption of energy, water, consumable materials/parts, emissions.
- Recommendations on the proper maintenance of the product, including information on which spare parts can be replaced, cleaning advice
- Information on the content in the product(s) purchased under this contract of Candidate List Substances of Very High Concern (SVHC) identified under Article 57 of Regulation (EC) No 1907/2006 (REACH regulation) in order for the contracting authority to take appropriate precautionary measures so that they can ensure that users of the product receive the information and can act accordingly

Verification:

A copy of the relevant pages of the instruction manual shall be supplied to the authority. The tenderer should also provide a declaration that this manual shall be available for access on the tenderer's or manufacturer's website, on a CD, or in paper format.

A list of the substances present in the product(s) purchased under this contract, which are included in the SVHC Candidate List, and complementary information according to Article 33 in REACH.

3. Product longevity and warranty

Repair or replacement of the product shall be covered by the warranty terms given by the manufacturer. The tenderer shall further ensure that genuine or equivalent spare parts are available (direct or via other nominated agents) for the expected service life of the equipment, at least for 5 years over warranty.

Verification:

The tenderer has to declare that the above clause will be met.

4. Training for energy efficiency optimisation

The tenderer shall provide training that includes elements regarding adjustment and fine-tuning of the equipment's electricity using parameters (for example, standby mode) in order to optimise the electricity use. The training can be included in the clinical and technical education to be provided by the tenderer.

Verification:

Description of the energy education training to be provided.

5. Installation with energy efficiency optimisation

The tenderer shall provide when installing the equipment, a needs assessment of the user (i.e. the ward) (for example frequency of use, type of examinations etc.). On the basis of the analysis, the tenderer shall provide documentation and information to the contracting authority on how to optimise the purchased equipment's electricity using parameters. If applicable, this process shall be repeated and revised at every preventive maintenance of the equipment done by the supplier.

Verification:

Description of the installation procedure and preventive maintenance procedure.

CONTRACT PERFORMANCE CLAUSE

6. Information on content of Candidate List Substances of Very High Concern

Within 5 years following the delivery of the product, the contracting authority shall be notified, within 6 months of the ECHA publishing a revised SVHC Candidate List, about the presence of one or several of the new substances on this list in all products under the contract, also regarding the results of the risk management file review, in order for the contracting authority to take appropriate precautionary measures, i.e. so that they can ensure that users of the product receive the information and can act accordingly.

AWARD CRITERIA

3.2 Energy performance requirements

The energy performance requirements are proposed as award criteria.

7. Energy performance of health care EEE except from CT, haemodialysis equipment, MRI, medical sterilizers and disinfectors

Points will be awarded according to the daily energy consumption **E (kWh)/day)**, as shown in the table below (the lower the daily energy consumption, the more points will be awarded).

Definitions of modes are according to Appendix 1. The proposed means of verification is indicated below the table.

For incubators and medical freezers, points will be awarded according to the daily energy consumption per volume, **E (kWh/day and m^3)**.

The procurer needs to indicate the expected daily use patterns of the equipment ("customised scenario"), the tenderer will need to state the energy use of the equipment in the different modes. The pre-determined use scenario is a recommendation to the procurer based on average use scenarios of European hospitals. The procurer is however free to adapt the use scenario to the specific needs.

Equipment	**Mode**	**Customised scenario** *Stated by procurer*	**Pre-determined use scenario** *Guidance*	**Energy in use phase** *Stated by tenderer*	**The Energy usage (E) calculation:**
Active Respiratory Gas Humidifier	Active	T_1= 24 hrs.	T_1 =24	P_1	(T_1*P_1) = **E (kWh) per day**
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 11.*	
Bed side monitoring equipment	Active	T_1 = 24 hrs.	T_1 = 24	P_1	(T_1*P_1)= **E (kWh) per day**
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 13.*	

Equipment	Mode	Customised scenario *Stated by procurer*	Pre-determined use scenario *Guidance*	Energy in use phase *Stated by tenderer*	The Energy usage (E) calculation:
ECG (Electro-cardio-graphic) **equipment (diagnostic)**	Active	T_1	$T_1 = 2$	P_1	$(T_1*P_1) + (T_2*P_2) + (T_3*P_3)$ = **E (kWh) per day**
	Standby *(for those having this mode)*	T_2	$T_2 = 2$	P_2	
	Off	T_3	$T_3 = 20$	P_3	
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 7.*	
Endoscopic equipment (camera unit, endoscope, light, air pump)	Active	T_1 =number of hours in this mode per day, with the following conditions specified for the light source by procurer: Lux= Light intensity Ra= Colour rendering index T°= Colour temperature (Kelvin), life span in hours	$T_1 = 5$	P_1	$(T_1*P_1) + (T_2*P_2)$ = **E (kWh) per day**
	Off	T_2	$T_2 = 19$	P_2	
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 8 and according to conditions specified by the procurer.*	

Equipment	Mode	Customised scenario *Stated by procurer*	Pre-determined use scenario *Guidance*	Energy in use phase *Stated by tenderer*	The Energy usage (E) calculation:
HF surgery, diathermy equipment	Active	T_1 = operation hours per day	$T_1 = 5$	P_1 = (measured with load 500 Ω for mono polar and 50 Ω for bipolar with duration time 30 seconds)	$(T_1*P_1) + (T_2*P_2)$ = **E (kWh) per day**
	Off	T_2 = operation hours per day	$T_2 = 19$	P_2	
	Definitions of modes according to appendix 1.		*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 6.*	
Incubator for babies (permanent)	Active	$T_1 = 24$ Specify: space for patients, e.g. space for patients up to 6 kg and length of 60 cm	$T_1 = 24$, incubator shall fit patients up to 6 kg and length of 60 cm	$E_{1=}(T_1*P_1)$ per V	$(T_1*P_1)/ V$ = **E (kWh) per day and m^3 of incubator**
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 9. V= volume(m3) of incubator fulfilling the conditions (space) specified by the procurer*	
Infusion pumps and syringe pumps	Active	T_1	$T_1 = 14$	P_1	$(T_1*P_1) + (T_2*P_2)$ = **E (kWh) per day**
	Off	T_2	$T_2 = 10$	P_2	
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 10.*	

Equipment	Mode	Customised scenario *Stated by procurer*	Pre-determined use scenario *Guidance*	Energy in use phase *Stated by tenderer*	The Energy usage (E) calculation:
Laser instruments for surgery, Continuous lasers	Active mode = Ready condition	T_1	$T_1 = 5$	P_1	$(T_1*P_1) + (T_2*P_2) + (T_3*P_3)$ = **E (kWh) per day**
	Standby = laser standby	T_2	$T_2 = 4$	P_2	
	Off	T_3	$T_3 = 15$	P_3	
	Definitions of modes according to appendix 1 and the active mode and standby mode are defined according to the definition in the standard SS-EN 60 601-2-22, 2.1.117 – stand-by/ready condition.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 12.*	
Medical freezers	Active	T_1 = 24 hrs. Specify: Useful capacity, the length, the width and the height of the inner volume = V, volume (m^3) of the freezer, as well as requested temperature.	$T_1 = 24$	P_1	$(T_1*P_1)/ V$ = **E (kWh) per day and m^3 of freezer**
	Definitions of modes according to appendix 1.	*T=time* *V= volume*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 17.*	

Equipment	Mode	Customised scenario *Stated by procurer*	Pre-determined use scenario *Guidance*	Energy in use phase *Stated by tenderer*	The Energy usage (E) calculation:
Medical lighting (surgical lamps)	Active	T_1= number of hours in this mode per day, with the following conditions specified by procurer: Lux= Light intensity Ra= Colour rendering index T°= Colour temperature (Kelvin) Life span in hours	T_1= 8	P_1 = measured for lamp type fulfilling the conditions specified by the procurer	(T_1*P_1) + (T_2*P_2) = **E (kWh) per day**
	Off	T_2	T_2= 16	P_2	
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 15.*	
Patient warming systems (blankets, pads, mattresses)	Active	T_1	T_1 = 9	P_1	(T_1*P_1) + (T_2*P_2) = **E (kWh) per day**
	Off	T_2	T_2= 15	P_2	
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 16.*	
With forced air device	Active	T_1	T_1 = 9	P_1+ P_F	(T_1*(P_1+ P_F)) + (T_2*P_2) = **E (kWh) per day**
	Off	T_2	T_2= 15	P_2	
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 16.* *P_F = power of the forced air device*	

Equipment	Mode	Customised scenario *Stated by procurer*	Pre-determined use scenario *Guidance*	Energy in use phase *Stated by tenderer*	The Energy usage (E) calculation:
Ultrasound equipment, excl. therapeutic	Scan / ready-to-scan	T_1	T_1= 6	P_1	(T_1*P_1) + (T_2*P_2) + (T_3*P_3) = **E (kWh) per day**
	Standby	T_2	T_2= 6	P_2	
	Off	T_3	T_3= 12	P_3	
	Definitions of modes according to COCIR SRI v1 (2009)	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 14.*	
	For battery powered ultrasound equipment: Energy consumption (kWh) to fully charge the battery: E_{charge} Daily Consumption for battery powered models: E_{charge}*3				
Ventilator , intensive care ventilator (excluding transport ventilator), anaesthesia ventilator (excluding home ventilators)	Active	T_1 = 24 hrs.	T_1 = 24	P_1	(T_1*P_1) = **E (kWh) per day**
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 18.*	
X-ray incl. mammo-graphy, excl. osteoporosis	Standby	T_1	T_1 = 15	P_1	(T_1*P_1) + (T_2*P_2) = **E (kWh) per day**
	Off	T_2	T_2= 9	P_2	
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*Recommended use scenario.*	*P= power (kW), Power measurements according to test conditions in appendix 3.*	

Verification:

Tenderers shall provide. a test report according to the standard EN 50564:2011 (6.1, 6.2, 6.3, and 6.4) or equivalent. The test report shall include energy performance data for the equipment. The data shall be measured in the modes and according to the test conditions in the appendices and use scenarios stated for each equipment above. The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, U.S. 21 CFR Part 820, ISO 13485 or equivalent according to the test conditions stated above.

8. Energy performance for Computed Tomography (CT)

Points will be awarded according to the daily energy consumption **E (kWh)/day)**, see below (the lower the daily energy consumption, the more points will be awarded).

Definitions of modes are according to Appendix 2.

The procurer needs to indicate the expected daily use patterns of the equipment ("customised scenario"), the tenderer will need to state the power consumption of the equipment in the different modes. The pre-determined use scenario is a recommendation to the procurer. The procurer is however free to adapt the use scenario to the specific needs.

Predetermined use scenario (to be used as the reference to compare CTs)

Tenderers shall state the daily energy consumption, **E (kWh)/day)**, for one of the 3 scenarios[2] according to the methodology and test conditions in the COCIR SRI for Computed Tomography Equipment, see www.cocir.org, or equivalent. The procurer states for which scenarios the energy consumption shall be provided.

- Scenario Off: energy consumption according to use scenario 20 scans per day with 12h in Off mode overnight
- Scenario Idle: energy consumption according to use scenario 20 scans per day with 12h in Idle mode overnight
- Scenario LowPower: energy consumption according to use scenario 20 scans per day with 12h in LowPower mode overnight

Customised use scenario

Tenderers deliver the following values according to the methodology and test conditions in the COCIR SRI for Computed Tomography Equipment, see www.cocir.org/site/index.php?id=46, or equivalent:

P_{Off} :Power consumption (kW) in Off mode

P_{Idle} : Power consumption (kW) in Idle mode

P_{Low}: Power consumption (kW) in Low Power mode

E_{Scan}: Energy consumption during abdomen scan

T_{Scan}: duration of abdomen scan (from prescription to power back in idle mode)

The daily energy consumption can be calculated with the following formula (values in *italics* to be determined by the purchaser, in **bold** declared by the supplier)

$$\mathbf{E=kWh/day} = \mathbf{P_{Off}} \times \mathit{T_{Off}} + \mathbf{P_{Low}} \times \mathit{T_{Low}} + \mathit{N_{Scan}} \times \mathbf{E_{Scan}} + \mathbf{P_{Idle}} \times (24h - \mathit{T_{Off}} - \mathit{T_{Low}} - \mathit{N_{Scan}} \times \mathbf{T_{Scan}})$$

Where:

N_{Scan} is the number of scans per day.

Considering the little influence of energy used in scan mode over 24 hours, results from the COCIR methodology have shown that energy usage for scan mode can be approximated by using the

[2] This provides the purchaser a good overview of the energy consumption and how much can be saved by using the equipped Off and Low Power modes

abdomen scan only.

$T_{Low,off}$ is time in hours per day for each mode.

T_{Scan} is time duration for each scan (stated by the tenderer).

Verification:
For CT: Tenderers shall provide a test report according to the COCIR SRI for Imaging Equipment, see www.cocir.org/site/index.php?id=46, or equivalent, showing the energy performance data.

The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, U.S. 21 CFR Part 820, ISO 13485 or equivalent according to the test conditions stated above.

9. Energy performance for haemodialysis equipment:

Points will be awarded according to the energy consumption per treatment, E (kwh) / treatment, and the test conditions below. (The lower the energy consumption per treatment, the more points will be awarded).

The treatment cycle shall be as follows, in accordance with IEC 60601-2-16 or equivalent:

- Test – time duration depends on machine
- Filling/Rinsing - 10 Minutes
- Pre-Circulation - 15 Minutes
- Dialysis- 4h
- Heat/Chemical Disinfection – time duration depends on machine *Type of disinfection to be stated by the procurer.*

The energy usage per treatment shall be measured according to test conditions specified in Appendix 5.

Points will be awarded if the dialysis equipment is equipped with an automatic function to reduce the dialysis flow during the time between priming and dialysis phase. The tenderer shall state the reduced dialysis flow. The larger the reduction of the dialysis flow, the more points will be awarded.

Points will be awarded if the dialysis equipment turns itself off when not in use within 10 minutes after the disinfection.

Verification:
Tenderers shall provide. a test report according to the standard EN 50564:2011 (6.1, 6.2, 6.3, and 6.4) or equivalent. The test report shall include energy performance data for the equipment. The data shall be measured in the modes and according to the test conditions and use scenarios stated above.
The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, U.S. 21 CFR Part 820, ISO 13485 or equivalent according to the test conditions stated above.

10. Energy performance for Magnetic Resonance Imaging (MRI)

Points will be awarded according to the daily energy consumption **E (kWh)/day)**, see below (the lower the daily energy consumption, the more points will be awarded).

Definitions of modes are according to Appendix 2.

The procurer needs to indicate the expected daily use patterns of the equipment ("customised scenario"), the tenderer will need to state the energy use of the equipment in the different modes. The pre-determined use scenario is a recommendation to the procurer. The procurer is however free to adapt the use scenario to the specific needs.

Predetermined use scenario (to be used as the reference to compare MRIs)

Tenderers deliver the daily energy consumption **E (kWh)/day)**, according to the methodology and test conditions in the COCIR SRI for Magnetic Resonance Imaging Equipment or equivalent, see www.cocir.org/site/index.php?id=46.

Customised use scenario

Tenderers deliver the following values according to the methodology and test conditions in the COCIR SRI for Magnetic Resonance Imaging Equipment, see www.cocir.org/site/index.php?id=46, or equivalent:

P_{Off} :Power consumption (kW) in Off mode

P_{Low}: Power consumption (kW) in Low Power mode

P_{Ready}: Power consumption (kW) in Ready-to-scan mode

E_{Scan}: Energy consumption during scan for 5 body regions (head, spine, abdomen, knee, angio)

T_{Scan}: duration of scan (including sequences scan time and a fixed ready-to-scan time defined in the COCIR methodology)

The daily energy consumption can be calculated with the following formula (values in *italics* to be determined by the purchaser, in **bold** declared by the supplier)

$$kWh/d = \mathbf{P_{Off}} \times \mathit{T_{Off}} + \mathbf{P_{Low}} \times \mathit{T_{Low}} + \mathit{N_{Scan}} \times \mathbf{E_{Scan}} + \mathbf{P_{Ready}} \times (24h - \mathit{T_{Off}} - \mathit{T_{Low}} - \mathit{N_{Scan}} \times \mathbf{T_{Scan}})$$

Where:

N_{Scan} is the number of scan for each body region: $\mathit{N_{Scan}} \times \mathbf{T_{Scan}} = \mathit{N_{Head}} \times \mathbf{T_{Head}} + \mathit{N_{Abdomen}} \times \mathbf{T_{Abdomen}} + \mathit{N_{Spine}} \times \mathbf{T_{Spine}} + \mathit{N_{Knee}} \times \mathbf{T_{Knee}} + \mathit{N_{Angio}} \times \mathbf{T_{Angio}}$.

$T_{low,\ off}$ is time in hours per day for each mode.

T_{scan} is time duration for each scan (stated by the tenderer).

Verification:

Tenderers shall provide. a test report according to the COCIR SRI for Imaging Equipment, see www.cocir.org/site/index.php?id=46, or equivalent, showing the energy performance data for the equipment.

The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, U.S. 21 CFR Part 820, ISO 13485 or equivalent according to the test conditions stated above.

11. Energy performance for medical sterilizers

Pre-determined use scenario

The capacity and the loading of a sterilizer both have an impact on the energy performance depending on the usage of the available capacity. The more goods that are sterilized with one single cycle, the lower the energy consumption per good. The energy consumption of sterilizers can be either rated based on the usable chamber volume in litres or on the maximum load capacity in kg. The tenderer shall state both criteria in numbers to give the contracting authority an average impression of energy consumption.

Points will be awarded according to the energy consumption per cycle , i.e.:

- how low the reported energy consumption per litre is, **EV (Wh /l)**, according to the test conditions in appendix 4.
- how low the reported energy consumption per load is, **EW (Wh /kg)**, according to the test conditions in appendix 4.

The lower the energy consumption per cycle, the more points will be awarded.

The tenderer will specify:

- energy consumption:
  EV for empty chamber
  EW for maximum load as specified in Appendix 4
- the usable chamber volume (in litres)
- the applied product standard (EN 13060 or EN 285)

Definitions of modes are according to Appendix 1.

The measurements shall be carried out according to the test conditions specified in Appendix 4.

Verification:

Tenderers shall provide energy performance data, EV and EW for the equipment, based on test protocols according to the standard EN 50564:2011 (6.1, 6.2, 6.3, and 6.4) or equivalent. The data shall be measured in the modes and according to the test conditions in appendix 4. The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, U.S. 21 CFR Part 820, ISO 13485 or equivalent according to the test conditions stated above.

Customised use scenario

Points will be awarded according to the daily energy consumption **E (kWh)/day)**, see table below (the lower the daily energy consumption, the more points will be awarded). Please, fill in the table below.

Definitions of modes are according to Appendix 1. Verification description can be viewed below the table.

Equipment	Mode	Customised use scenario *Stated by procurer*	Energy in use phase *Stated by tenderer*	The Energy usage (E) calculation:
Medical sterilizer	Active	N= Number of specified cycles per day *(Specify: L= load per cycle (kg), M= material type (metal or textile), T=Type of cycle (sterilizing T°), drying stage used (yes/no))*	E_1 = Energy usage (kWh) per cycle based on the specified cycle stated by the procurer	$[\sum (N_1*E_1)] + (T_2*P_2) + (T_3*P_3)$ = **E (kWh) per day**
	Ready	T_2	P_2	
	Standby	T_3	P_3	
	Definitions of modes according to appendix 1.	*T=time, number of hours in the current mode per day*	*P= power (kW), Power and Energy usage measurements according to test conditions in appendix 4.*	

The measurements shall be carried out according to the test conditions specified in Appendix 4.

Verification:

Tenderers shall provide a test report according to the standard EN 50564:2011 (6.1, 6.2, 6.3, and 6.4) or equivalent. The test report shall include energy performance data EV and EW. The data shall be measured in the modes and according to the test conditions in appendix 4 and to the use scenarios stated by the procurer. The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, U.S. 21 CFR Part 820, ISO 13485 or equivalent according to the test conditions stated above.

12. Energy performance for flusher and washer disinfectant equipment

Points will be awarded according to the energy consumption per cycle, **E (kwh) / cycle**, see below (the lower the energy consumption per cycle, the more points will be awarded).

The procurer states the type of disinfector to be procured:

- Disinfector for flexible endoscopes
- Disinfector for all other instruments (General surgical instruments, MIS, Anaesthetics, Orthopaedics, etc.)
- Disinfector for bulky goods like Sterile Containers, Trolleys, OP-Theatre-Shoes, etc.
- Disinfector for human waste containers

and needs to specify the following:

- Specific required load (amount of load)
- Drying stage used (Yes/No)
- HW (Hot Water) (Yes/No)
- Treated Water in Final rinse (Yes/No)
- Heating methods (Steam or Electrical)
- Voltage

Measurements shall be carried out by manufacturer according to:
A0 Value:

- Disinfector for surgical and analytical instruments: A0 3000
- Disinfector for Instruments and bulky goods: A0 600
- Disinfector for human waste containers: A0 60

- CW (Cold Water) Max temperature 20°C
- HW (Hot Water) Max temperature 60°C
- Treated Water Max temperature 20°C
- Steam Max 500 kPa

Additional test conditions for energy performance measurements are found in Appendix 3.

The manufacturer states what acceptance criteria is for cleaning, disinfection and drying performance in accordance to EN ISO 15883.

The tenderer states the energy performance per cycle, based on above parameters.

Verification:

Tenderers must provide a test report with included water consumption data and energy performance for the equipment, also demonstrating that the above standards and test conditions or equivalent are met.

The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, U.S. 21 CFR Part 820, ISO 13485 or equivalent according to the test conditions stated above.

13. Automatic low power mode for medical sterilizer, disinfector, CT, ECG diagnostic, MRI, and ultrasound

Points will be awarded if the equipment can be configured to go automatically into a standby or off mode after a certain period of inactivity or after a predetermined schedule, according to the pattern below**.** For CT and MRI points will be awarded if the scanner is equipped with a low power mode which can be activated by the operator:

Equipment	**From mode**	**To mode**
Medical sterilizer and disinfector	Ready mode	Standby mode
CT	Idle	Low power mode
ECG, diagnostic	Active or standby mode	Off mode
MRI	Ready-to-scan mode	Low power mode
Ultrasound	Ready-to-scan mode (The ultrasound unit is on and ready to acquire the image. All modules except the ones needed for the scan are on (the transducer is not activated).	Standby mode

Points will also be awarded if the equipment has a short and automated start-up to full functionality after its automatic function according to above has been activated. Specify the time in seconds and the active efforts required of the staff. The shorter time and the smaller active efforts needed, the more points will be awarded.

Definitions of modes are according to appendix 2 for CT and MRI and according to appendix 1 for the remaining equipment above.

Verification:

Tenderers shall provide documentation such as a copy of the instruction manual, describing:

- the required automatic low power or off mode according to the above pattern, how it can be activated by the operator and the available configuration options, including individualized automatic behaviour and functions or description on how to best use low power modes to save energy, and
- the start-up time with its required active efforts of the staff

The tenderer shall declare that this documentation will be available for access on the tenderer's or manufacturer’s website, on a CD, or in paper format.

14. Equipment with a metering device

Points will be awarded if the equipment has or can be equipped with a metering device, so that a log of the current consumption (of electricity, water (if relevant), and gas (relevant for anaesthesia and intensive care equipment)) can be observed and registered. The user should also be able to obtain statistics from historic consumption in report form. The tenderer shall state the conditions for consumption metering, as well as if additional cost will be applied[3]. The tenderer shall also state the restrictions regarding what or how the staff can measure with the metering device.
Points will be awarded if the acquired data can automatically be sent to a central point of data gathering.

Verification:

Tenderers shall provide documentation such as a copy of the instruction manual, describing the metering device and its functions, conditions and restrictions.

3.3 Water efficiency requirements for different types of equipment

15. Water consumption for haemodialysis equipment

Points will be awarded according to the water consumption per treatment (the lower the water consumption, the more points will be awarded).

The treatment cycle shall be as follows, in accordance with IEC 60601-2-16 or equivalent:

- Test – time duration depends on machine
- Filling/Rinsing - 10 Minutes
- Pre-Circulation - 15 Minutes
- Dialysis- 4h
- Heat/Chemical Disinfection – time duration depends on machine *Type of disinfection to be stated by the procurer.*

Points will be awarded for equipment with a low water consumption function (at least 50 % reduction of the water consumption for the pre-circulation phase).

Points will be awarded for equipment with a no water consumption function during standby (100 % reduction in saving mode).

Contracting authorities will have to indicate in the contract notice and tender documents how many points will be awarded for each award criterion.

Verification:

Tenderers must provide a test report with included water consumption data according to test conditions specified in IEC 60601-2-16 or equivalent and relevant pages of or link to instruction manual covering the low and no water consumption functions, also demonstrating that the above standards and test conditions or equivalent are met. The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, U.S. 21 CFR Part 820, ISO 13485 or equivalent according to the test conditions stated above.

[3] The cost will be assessed in the overall Life Cycle Costing of the equipment, together with all other costs.

16. Water consumption for flusher and washer disinfectant equipment

Points will be awarded according to the water consumption per cycle, according to test conditions specified below (the lower the water consumption per cycle, the more points will be awarded).

The procurer states the type of disinfector to be procured:

- Disinfector for flexible endoscopes
- Disinfector for all other instruments (General surgical instruments, MIS, Anaesthetics, Orthopaedics, etc.)
- Disinfector for bulky goods like Sterile Containers, Trolleys, OP-Theatre-Shoes, etc.
- Disinfector for human waste containers

And needs to specify the following:

- Specific required load (amount of load)
- Drying stage used (Yes/No)
- HW (Hot Water) (Yes/No)
- Treated Water in Final rinse (Yes/No)
- Heating methods (Steam or Electrical)
- Voltage

Measurements shall be carried out by manufacturer according to:
A0 Value:

- Disinfector for surgical and analytical instruments: A0 3000
- Disinfector for Instruments and bulky goods: A0 600
- Disinfector for human waste containers: A0 60

- CW (Cold Water) Max temperature 20°C
- HW (Hot Water) Max temperature 60°C
- Treated Water Max temperature 20°C
- Steam Max 500 kPa

The manufacturer states what acceptance criteria is for cleaning, disinfection and drying performance in accordance to EN ISO 15883.

The tenderer states the water consumption per cycle, based on above parameters.

Verification:

Tenderers must provide a test report with included water consumption data and energy performance for the equipment, also demonstrating that the above standards and test conditions or equivalent are met.

The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, U.S. 21 CFR Part 820, ISO 13485 or equivalent according to the test conditions stated above.

Comprehensive criteria (proposed for use in addition to core criteria)
AWARD CRITERIA
17. Refrigerants in medical freezers Points will be awarded if the equipment contains refrigerants with GWP_{100} (Global Warming Potential) < 10. **Verification:** Documentation stating the refrigerants used in the medical freezer and their GWP_{100}, proving that the above criterion is fulfilled.
18. Gas consumption for anaesthesia equipment – low flow equipment Points will be awarded for anaesthesia equipment for long and medium term treatment, that are equipped with back pressure compensated low-flow[4] function of no more than 2 litres. Points will be awarded for anaesthesia equipment with features which automatically drive to low flow (automatic low flow function) or provide informational tools which aid the clinician (a guiding user interface) in achieving low flow. **Verification:** A copy of the relevant pages of the instruction manual, describing the required low-flow adjustment and features for automatic low flow or informational tools, shall be supplied to the authority. This manual shall be available for access on the manufacturer's website, on a CD, or in paper format.

3. Explanatory notes

Award Criteria

Contracting authorities will have to indicate in the contract notice and tender documents how many points will be awarded for each award criterion. Environmental award criteria should, altogether, account for at least 15% of the total points available.

4. Cost considerations

Life cycle costing

Energy and water consumption can also be used in Life Cycle Cost (LCC) calculations. In this case, the public authority could calculate the water and energy spending over the expected lifetime of the equipment and include them in the price of the tender. Usually the cost of operation, maintenance, and disposal costs exceed all other first costs many times over (supporting costs are often 2-20 times greater than the initial procurement costs). If LCC is used in such a way, double counting must be avoided, i.e. that a lower energy and water consumption should not be awarded points twice but only

4 Low Flow: A flow rate that gives adequate O2 and agent to the patient with a good response time to changes; maximum 2 litres per minute in clinical studies (in normal operating mode the typical value is 4-5 litres).

in the framework of LCC or as an award criterion in addition to the price (without the costs for energy and water included).

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Benefits

Below are given some examples of environmental and economic benefits for sustainable health care EEE which can be achieved by good performers on the market. These are rather examples to illustrate an overview of possible benefits (i.e. that benefits are possible at all) than detailed descriptions which take into consideration which exact examination or operating mode is performed, which comparison is made, or which exact model is described. Benefits are in comparison with either a predecessor, a standard model or similar models on the market. Sources of information are product declarations collected from the suppliers' web sites and questionnaire results from the RFI (Request For Information) in the market analysis.

Example of health care EEE	Environmental benefit	Economic benefit
CT	• Energy savings of 50 % during thorax examinations • Energy savings of 80 % during cardiac examinations • (Energy savings of 50 % in daily energy consumption) • 33,000kWh per machine annually, 15 tons of CO2 emissions, equivalent to the annual CO2 emissions of 4 cars	• Annual savings of up to € 3700 per CT system
Dialysis	• 50% less energy usage • 30% water reduction (of normal use of 500 l per treatment)	• 50% less operating costs
ECG	• 10% less energy usage	
Mammography	• 50% reduction in energy use	
Medical lighting – surgical lamp	• 50% (switch from halogen to LED)	• Savings of 0.03 TWh annually in the USA (as an example)
Monitoring equipment	• 50% less energy usage	
MRI	• 50% less energy usage (business as usual: operating an MRI can produce about 90 tons of CO_2 annually) • Reduces annual electricity usage by about 60,000 kWh, equivalent to the annual electricity consumption of 5 households, 27 metric tons of CO_2, equivalent to the annual emissions of 7 cars	• Annual savings of up to € 6700 per MRI
Ultrasound Equipment	• Energy savings of 90%	• 1,300 kWh less electricity per year per US
Sterilizer	• 20 % more energy efficient	
X-ray	• 80 % more energy efficient	

5. Appendices

Appendix 1

The modes are defined as follows, according to EN 50564:2011 and EC 1275/2008:

'active mode(s)' means a condition in which the equipment is connected to the mains power source and at least one of the main function(s) providing the intended service of the equipment has been activated;

'ready mode(s)' means a condition in which the equipment is connected to the mains power source and provides (immediate) activation of all available functions.

'standby mode(s)' means a condition where the equipment is connected to the mains power source, depends on energy input from the mains power source to work as intended and provides only the following functions, which may persist for an indefinite time: reactivation function, or reactivation function and only an indication of enabled reactivation function, and/or information or status display;

'off mode' means a condition in which the equipment is connected to the mains power source and is not providing any function; the following shall also be considered as off mode:

(a) conditions providing only an indication of off-mode condition;

(b) conditions providing only functionalities intended to ensure electromagnetic compatibility pursuant to Directive 2004/108/EC of the European Parliament and of the Council (1);

'**reactivation function'** means a function facilitating the activation of other modes, including active mode, by remote switch, including remote control, internal sensor, timer to a condition providing additional functions, including the main function;

'**information or status display'** means a continuous function providing information or indicating the status of the equipment on a display, including clocks;

Appendix 2

CT

The modes are defined according to the COCIR SRI document: CT measurement on energy consumption methodology"

Off mode: The system is shut down, AC mains off, according to the user manual. The system consumes no energy.

Low-power mode: The system is running in the minimum energy consumption state that the user can select according to the user manual.

Idle mode: A state of the system when fully powered but no scan has been prescribed. This mode does NOT include x-ray tube rotor or gantry rotation.

Scan mode: A state of the system between individual scans and during scans (e.g. during patient handling, examination planning, contrast agent injection and active scanning with x-ray generation). This mode includes tube rotor rotation, gantry rotation and generation of image, and any possible idle between scans.

MRI

The modes are defined according to the COCIR SRI document: “MRI measurement on energy consumption methodology”

Off mode: The system is running in the minimum energy consumption state that the typical user can access, "off" or "shutdown" has been selected at the operator console.

Ready-to-scan mode: This mode represents the state of the system between individual scans (e.g. during patient handling, data archiving, examination planning or contrast agent injection).

Scan mode: The MRI is actively scanning the patient to generate images by sending and receiving RF energy and switching the magnetic field gradients. The computing system interprets the data and generates the image.

Low power mode: This operator selected mode represents a state of the system with power consumption lower than ready-to-scan and higher than off mode. (i.e., sleep mode, service/evaluation mode).

Appendix 3

X-ray, Washer Disinfector, Flusher Disinfector

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Appendix 4

Medical sterilizers

Pre-determined use scenario, test conditions

The type of cycle to be used shall comply with either EN 285 or EN 13060 or equivalent, according to the volume stated by the procurer.

EV definition for EN 13060 or EN 285 compliant sterilizer

EV=E/V (kWh/litre)

E=Energy consumption in kWh per cycle run with empty chamber

V=Maximum usable volume of sterilizer in litres.

EW definition for EN 13060 or EN 285 compliant sterilizer:

EW=EM/M (kwh/kg)

EM=Energy consumption in kWh per cycle with test load M (kg)

M=Test metal load as stated by the supplier (kg)

For EN 13060 compliant sterilizer the test load is the maximum metal load stated by the supplier (kg).

For EN 285 compliant sterilizer the test load is 15 kg metal load x STE (while STE is the maximum usable volume stated by the manufacturer)

Note: The metal used in the test load shall be stainless steel according to EN 10088-1.

Note: The energy performance data are valid for a 134 ^{o}C wrapped goods cycle

The sterilizer shall be pre-heated and ready to use.

The test shall be performed with active drying.

The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s, according to the standard EN 50564:2011; 4.2 Test room. The ambient temperature shall be maintained at (23 ± 2) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Customised use scenario, test conditions

The sterilizer shall be pre-heated and ready to use.

The energy performance shall be measured according to the procurer's specified conditions such as if active drying is included, load per cycle, material type, type of cycle.

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other conditions

During the tests the temperature of incoming water shall be 15 degrees according to EN 285:2006 or equivalent. The sterilization/ disinfection result shall comply with prevailing standards.

Appendix 5

Dialysis equipment

Test conditions

According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s.

The ambient temperature shall be maintained at (23 ± 2) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

During the tests the temperature of incoming water shall be 15 degrees.

Other test conditions regarding the dialysis phase:

The operating conditions during measurement of energy performance of the haemodialysis equipment in the dialysis phase shall be according to the standard IEC 60601-2-16 or equivalent:

Dialysing fluid flow: 500 ml/min;

Blood flow: 300 ml/min;

Ultrafiltration flow: 0,5 l/h;

Dialysing fluid temperature: 37 °C

Appendix 6

HF, RF Surgery, diathermy equipment

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test. The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other test conditions for active mode

The test shall be carried out according to the standard EN 60601-2-2, or equivalent:

Maximum temperature during normal use addition duty cycle: HF surgical equipment, set up to deliver output power of 50 W into a resistive load using the electrode cable, is operated for 1 h with a duty cycle as specified by the manufacturer but with operating times of at least 10 s alternating with a resting time of not more than 30 s.

Max load shall be 500 Ω for mono polar and 50 Ω for bipolar with a duration of 30 seconds.

The steps below shall be followed according to the standard EN 50564:2011, (5.2 Preparation of product), or equivalent:

– determine if the product contains a battery and whether the product contains circuitry for recharging a rechargeable battery. Reference shall be made to determine whether there is a legal provision which specifies the conditions to be applied, otherwise the following shall apply. For products containing a recharging circuit, the power consumed in – off mode and standby mode shall be measured after precautions have been taken to ensure that the battery is not being charged during the test, e.g. by removing the battery where this is possible, or ensuring that the battery is kept fully charged if the battery is not removable;

– a maintenance mode shall be measured with the batteries installed and fully charged before any measurements are undertaken.

Appendix 7

ECG equipment

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other test conditions for active mode

The test shall be carried out during a measurement cycle over a period of 15 minutes and the following values shall be achieved and recorded during the test.

Sinus rhythm: 60 BPM

ECG-amplitudes: 1 mV

Appendix 8

Endoscopic equipment

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

The test object/product: The endoscopic equipment shall be consisting of a light source (on maximum power), camera unit, endoscope, and air pump during the test. The light source must have reached working temperature before start of test.

Appendix 9

Incubator for babies (permanent)

Test conditions

According to the standard for infant incubator EN 60601-2-19; 201.5.3 Ambient temperature, humidity, atmospheric pressure or equivalent:

If not otherwise specified in this particular standard, all tests shall be carried out at an ambient temperature within the range of 21 °C to 26 °C.

The test shall be carried out at an ambient temperature of 21 °C to 26 °C with an operating time of one hour and the control temperature (temperature selected at the temperature control) shall be 36 °C. See further information in Clause 201.12.1.101 Stability of incubator temperature. Temperature shall have stabilized before the test starts.

The steps below shall be followed according to the standard EN 50564:2011, (5.2 Preparation of product), or equivalent:

– determine if the product contains a battery and whether the product contains circuitry for recharging a rechargeable battery. Reference shall be made to determine whether there is a legal provision which specifies the conditions to be applied, otherwise the following shall apply. For products containing a recharging circuit, the power consumed in

– off mode and standby mode shall be measured after precautions have been taken to ensure that the battery is not being charged during the test, e.g. by removing the battery where this is possible, or ensuring that the battery is kept fully charged if the battery is not removable;

– a maintenance mode shall be measured with the batteries installed and fully charged before any measurements are undertaken.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Appendix 10

Infusion pumps

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other conditions

The test shall be achieved and recorded at the intermediate rate for a period of 120 minutes at back pressures of ± 13,33 kPa (± 100 Hg), according to the standard EN 60601-2-24 or equivalent.

Appendix 11

Active respiratory gas humidifier

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other test conditions

The test shall be carried out according to EN ISO 8185, or equivalent, with a minimum water content of respired respiratory gas of ca. 33 mg/dm³ and a maximum respiratory gas temperature of ca. 42 °C

The test shall be carried out without heating coil.

The flow shall be 10 litres/ minute, and the ventilator connected with the active respiratory gas humidifier shall be adjusted to tidal volume 500 ml and breathing frequency of 20/min and air, i.e. 30% oxygen volume controlled mode, according to the standard EN ISO 80601-2-12, 201.12.1.101, or equivalent.

Appendix 12

Laser instruments

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test. The laser shall be in standby mode according to the definition in the standard EN 60 601-2-22 or equivalent during measurement of the energy consumption in the standby mode.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other conditions

The laser shall be in ready condition according to the definition in the standard EN 60601-2-22 or equivalent at 15 minutes during measurement of energy consumption in the active mode.

Modes definitions from EN 60601-2-22:

Stand-by condition: The mains cable is connected and the mains switch activated. The laser is not capable of emitting the working beam even if the laser control switch is activated. Ready condition: The laser equipment is capable of emitting laser output when the control switch is activated.

Appendix 13

Bed side monitoring equipment

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2., in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The steps below shall be followed according to the standard EN 50564:2011, (5.2 Preparation of product), or equivalent:

– determine if the product contains a battery and whether the product contains circuitry for recharging a rechargeable battery. Reference shall be made to determine whether there is a legal provision which specifies the conditions to be applied, otherwise the following shall apply. For products containing a recharging circuit, the power consumed in

– off mode and standby mode shall be measured after precautions have been taken to ensure that the battery is not being charged during the test, e.g. by removing the battery where this is possible, or ensuring that the battery is kept fully charged if the battery is not removable;

– a maintenance mode shall be measured with the batteries installed and fully charged before any measurements are undertaken.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other test conditions

During the measurement of energy performance in the active mode, the Input signals in the range of ± 5 mV, varying at a rate to 125 mV/s, shall be reproduced on the output, this according to IEC 60601-2-27, 201.12.1.101.1, or equivalent.
The monitor must have reached working temperature before start of test.

Appendix 14

Ultrasound equipment

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2., in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other test conditions

The ultrasound system shall be equipped with a standard 5 MHz probe or equal.

Use a standard test phantom like RMI403GS or likewise.

Scan the phantom with 2D scanning mode using a sending frequency as close as possible to 5 MHz. Adjust an appropriate image on 10cm depth.

Measure the energy consumption during 30 min of continues scanning with the parameters above.

Appendix 15

Medical lighting – surgical lamps

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

Other conditions

According to the standard EN 60601-2-41, 201.5.4 other conditions:

In order to measure stabilized performances, the output values shall be measured after a pre-ageing period, depending on the light source technology, at rated voltage under normal conditions.

This pre-aging period is:

3 h for halogen lamp and LED;

50 h for discharge lamp;

for other light sources, the pre-aging period after which the performances variation does not exceed 1% per 100 h.

The light source must have reached working temperature before start of test.

Appendix 16

Patient warming systems

Test conditions

The methodology for power measurements shall be according to the sampling method 5.3.2., in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, , the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test. The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other test conditions:

The test object/product: The blanket without forced air device

The test room conditions shall be: ambient temperature at 23 °C +/-2 °C in a room with an air velocity of less than 0,1m/s, according to EN 80601-2-35 Annex CC, or equivalent.

Measurement of the energy performance for active mode:

Operate the heating device, as specified in EN 80601-2-35, 201.11.1.2.1.101.1 or equivalent, until a steady contact surface temperature of 36 °C is attained. In addition to section 201.11.1.2.1.101.1, section 201.12.4 describes further the measurement procedure:

Four temperature sensors conductively attached to copper plates 65 mm*65 mm*0,5 mm, are placed on the contact surface at the midpoints of the four rectangles formed by bisecting the length and the width of the contact. The temperature control is set so that the contact surface temperature reaches 36 °C. Temperature readings are taken at least every 10 min for 60 min. From these the values of the individual average temperatures at T1 to T4 are calculated and compared with the average values of the contact surface temperature.

From annex CC, the procedure uses the temperature rise after 1 h in a water-filled plastic bag under stated conditions, as an indicator of the heat transfer from the heating device to the patient. Heat transfer should be kept at 115 W/m2, which corresponds to an increase of the temperature of 2 l of water in a plastic bag by 1 °C in 1 h, when an area of 200 cm2 of the bag is in contact with the surface of the heating device.

Measurement of the energy performance for active mode for forced air device:

During the power measurement in the active mode of a forced air device, the forced air device shall be connected to a torso blanket that has reached a stabilized temperature of 38°C and the test duration shall be 1 hour.

Appendix 17

Medical freezer

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Temperature shall have stabilized before the test starts.

The freezer shall be empty, with no interior/fittings during the test and according to specified useful capacity, inner volume and requested temperature over a period of 24 hours. No freezer door openings shall occur during the measurement.

Appendix 18

Ventilator

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to the standard EN 50564:2011; 4.2 Test room, the tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

The equipment shall be pre-heated and ready for use, and adjusted according to the standard EN ISO 80601-2-12 or equivalent, 201.12.1.101 Volume-controlled breath type.

The measurement's duration shall be 15 minutes and the average power shall be registered.

Appendix 19

CAS: Chemical Abstracts Service

COCIR: European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

CT: Computed Tomography

ECG: Electrocardiographic

EEE: Electrical and electronic equipment

GHG: Green House Gas

GPP: Green Public Procurement

GWP: Global Warming Potential

HF: High frequency

LCC: Life Cycle Costing

LED: Light-Emitting Diode

MRI: Magnetic Resonance Imaging

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

RF: Radio frequency

SRI: Self-Regulatory Initiative